K020927

MAY 1 6 2002

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens

1. Submitter Information:

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Contact Person: Debra Ketchum
Manager, Regulatory Affairs
Telephone No.: (585) 338-8638

2. Device Name:

Classification Name: Soft (hydrophilic) contact lens

Proprietary Name: BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens

3. Predicate Devices:

Optima™ FW (polymacon) Visibility Tinted Contact Lens	(N16-895)
Unilens EMA (polymacon) Soft Bifocal Contact Lens	(K960926)
Acuvue Bifocal (etafilcon A) Contact Lens	(K962804)

4. DESCRIPTION OF DEVICE

The BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens is a hemispherical flexible shell which covers the cornea and may cover a portion of the adjacent sclera. It consists of a polymer of hydroxyethyl methacrylate (HEMA) and crosslinked with Ethyleneglycol Dimethacrylate (EGDMA), and is 38% water by weight when immersed in a sterile saline solution. This lens is tinted blue with Reactive Blue Dye 246 ((1,4-Bis[4-(2-methacryloxyethyl) phenylamino] anthraquinone). The color additive conforms with 21 CFR Part 73.3106.

The physical / optical properties of the lens are:

Specific Gravity:	1.15
Refractive Index:	1.4375
Light Transmittance:	C.I.E. Y value - at least 96%
Water Content:	38%
Oxygen Permeability (Dk):	8.4×10^{-11} $[cm^3 O_2 (STP) \times cm]/(sec \times cm^2 \times mmHg)$ @35°C (Polarographic Method)

The BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:

- Diameter: 13.5mm to 15.5mm
- Center Thickness: 0.05mm to 0.75mm
- Base Curve: 7.5mm to 9.5mm
- Powers (Spherical): +20.00D to -20.00D
- Add Power +1.00D to +5.00D

Each BAUSCH & LOMB® SofLens™ Multifocal (polymacon) Visibility Tinted Contact Lens is supplied in a plastic blister container with a saline solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere power, diameter, add (high/low) and expiration date.

5. INDICATIONS FOR USE

BAUSCH & LOMB® SofLens™ MulfiFocal (polymacon) Visibility Tinted Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens provides a power range of +20.00 to -20.00 diopters with add power ranging from +1.00D to +5.00D.

Replacement schedules may vary from patient to patient, and should be decided by eye care practitioners in consultation with their patients. The lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

6. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE

A series of non-clinical laboratory testing and clinical testing was performed to demonstrate the safety and effectiveness of the BAUSCH & LOMB® SofLens Multifocal (polymacon) Contact Lens. A summary of results from the preclinical and clinical tests is provided below.

Non-Clinical Laboratory Testing:

A series of *in vitro* and *in vivo* preclinical toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens device. Testing was performed in accordance with FDA guideline titled Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994. All non-clinical laboratory studies were conducted in compliance with the GLP regulation. The non-clinical laboratory testing can be found in N16-895, Supplement 74, approved August 13, 1991.

Stability testing has demonstrated a three year expiration date for the sterile lenses.

Clinical Testing:

A one month, randomized clinical study was completed to evaluate the safety and efficacy of the Bausch & Lomb Castmold Bifocal Contact Lens (Test) compared to the Johnson & Johnson Acuvue® Bifocal Contact Lens (Control) when worn on a daily wear basis.

At the Initial Dispensing Visit, eligible patients were dispensed a Bausch & Lomb Castmold Bifocal (Test) Contact Lens or Johnson & Johnson Acuvue® Bifocal (Control) Contact Lens according to randomization tables supplied to the Investigators. The identity of the study sponsor was not revealed to the patient. A total of 170 eyes (85 patients) were entered into the study by 6 Investigators. Of the 170 eyes (85 patients) enrolled, 166 eyes (83 patients) completed the study.

The primary endpoints were:

- Safety: No statistical differences between the study lenses with respect to the frequency of occurrence of total grade 2 or greater positive slit lamp findings.
- Efficacy: No statistical difference in the proportion of lens visual acuities worse than 20/40 between the Test and Control lenses.

There were no significant differences between the Test and Control lenses with respect to the frequency of occurrence of total grade 2 or greater slit lamp findings. Therefore, the safety end-point defined in the protocol was achieved.

There were no significant differences in the proportion of lens visual acuities worse than 20/40 between Test and Control lenses. Therefore, the efficacy end-point defined in the protocol was achieved.

The Sponsor concludes, based on the data presented, that the protocol-specified endpoints were achieved, and that the Bausch & Lomb Castmold Bifocal Contact Lens is equivalent in safety and efficacy to the Johnson & Johnson Acuvue Bifocal Contact Lens, when worn on a daily wear basis. The Castmold Bifocal Contact Lens is a safe and effective means of daily wear vision correction.

Substantial Equivalence

The BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens is similar to the BAUSCH & LOMB® Optima FW (polymacon) Visibility Tinted Contact Lens, in that both fall into the same FDA material classification grouping (Group I), have the same USAN name and both are manufactured by the same manufacturing process (castmolding). The BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens is different from the BAUSCH & LOMB® Optima FW (polymacon) Visibility Tinted Contact Lens in that it has a multifocal indication. The BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens is similar to the Unilens EMA (polymacon) Soft Bifocal Contact Lens, in that both fall into the same FDA material classification grouping (Group I), have a multifocal indication and have the same USAN name. The BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens is similar to Acuvue Bifocal (etafilcon A) Contact Lens in that both have the same multifocal indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2002

Ms. Debra L. Ketchum
Manager, Regulatory Affairs
Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Re: K020927
Trade/Device Name: BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens
Regulation Number: 886.5925
Regulation Name: Soft (hydrophilic) contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 19, 2002
Received: March 21, 2002

Dear Ms. Ketchum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Indications for Use Statement

510(k) Number (if known): K020927

Device Name: BAUSCH & LOMB® SofLens™ MultiFocal (polymacon) Visibility Tinted Contact Lens

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K020927